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10/627,143

07/25/2003

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/627,143 | SPECTOR ET AL. | |
| | Examiner | Art Unit | |
| | SUSAN HANLEY | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-37 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37 are pending.

Claims 1-26 stand withdrawn.

Claims 27-37 are under examination.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 8/25/09.

Claim Objections

Claim 27 is objected to because it includes reference characters (e.g., "A.", "B.", etc.) which are not enclosed within parentheses.

Claim 27 is objected to because "acrylamido" is misspelled (line 8).

Claim Rejections - 35 USC § 112

Claims 27-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 27 recites "reacting said biomolecule to be assayed with a second crosslinker and said hydrogel thereby forming a covalent bond between said biomolecule and said second crosslinker and a covalent bond between said second crosslinker and said hydrogel". This arrangement of bonding is New Matter. The specification discloses that there are three method for incorporating biomolecules into the sugar-containing hydrogels (specification page 3; however, the specification only teaches two main methods). Firstly, oligonucleotides

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(biomolecule) having a terminal acridine unit are polymerized with a sugar compound having a polymerizable double bond and a crosslinker having at least two polymerizable double bonds. This provides a direct covalent link to the acrylate backbone. In the second case, a sugar compound having a polymerizable double bond is reacted with a crosslinker having at least two polymerizable double bonds and a third compound having a polymerizable double bond and a group that allows for covalent attachment to biomolecules. The third compound can have an amino group, such as N-3-(aminopropyl)methacrylamide, wherein the amino group reacts with a functionalized biomolecule. The termonomer can have a carboxylic group, such as N-(3-carboxypropyl) methacrylamide to react with amino groups on the biomolecules. The termonomer can have an aldehyde group, such as N-(5,6-di-*O*-isopropylidene) hexacrylamide to react with aminated biomolecules. Neither method teaches a terpolymer having a poly(6-acryloyl-beta-*O*-ethyl monosaccharide), a crosslinker with two or more polymerizable double bonds and 2-acrylamido hydroxyacetic acid and a second crosslinker that is bound to the biomolecule. In any case, in the presence of a termonomer, the termonomer is linked to the biomolecules directly, there is no bond to a first or second crosslinker.

It is noted that in the case of a method for assaying a biomolecule comprising functionalizing a support with acrylate groups and forming a polyacrylate by reacting said acrylate groups on the support with a hydrogel polymer that contains poly(6-acryloyl-beta-*O*-methyl monosaccharide) and is the polymerization reaction product of a polyacrylate with a polymerizable double bond, a crosslinker with two or more polymerizable double bonds, and 2-acrylamido hydroxyacetic acid, reacting the biomolecules to be assayed with the hydrogel to form a covalent bond between said biomolecule and said hydrogel through the 2-acrylamido

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hydroxyacetic acid and assaying the biomolecule bonded to the hydrogel, such an embodiment would be obvious in view of Boschetti et al. (US 2003/0218130; previously cited) and Chen et al. (1995). Boschetti teaches assaying a biomolecule that is linked to a hydrogel (abstract; section [0009]) that is formed by reacting a substrate that can be glass (section [0063]) having acryloyl groups (section [0070]) with a polysaccharide having acryloyl groups (section [0075]), a crosslinker and a functionalized polymerizable monomer to which the biomolecule can be bound. The functionalized polymerizable monomer can be 2-acrylamidoglycolic acid (2-acrylamido hydroxyacetic acid; section 0082)]. The polymerization of the acryloyl groups makes a polyacrylate. The biomolecule is attached to the functionalized group and then assayed by a method such as an optical method (section [0137]). Boschetti does not disclose that the polyacrylate contains poly(6-acryloyl-beta-O-methyl monosaccharide but Chen et al. disclose the synthesis and characterization of poly(alpha-methyl galactoside 6-acrylate) hydrogels that are crosslinked that have application as a water absorbents and a biocompatible materials (abstract). Although Chen et al. disclose the alpha-methyl anomer, the beta methyl anomer is an obvious variant for the polymer.

It would have been obvious to one of ordinary skill in the art, a biochemist, at the time the invention was made to substitute a poly(6-acryloyl-beta-O-methyl galactoside) hydrogel polymer for the polyacrylate dextran hydrogel polymer taught by Boschetti for the claimed method. The ordinary artisan would have been motivated to do so because each composition is known to have the same function, acting as a hydrogel polymer. Hence, the substitution is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another for a predictable result.

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The ordinary artisan would have had a reasonable expectation that one could make the substitution because the polymer taught by Chen et al. has hydrogel properties.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 30 is drawn to a hydrogel polymer having a pore size of 0.1 to 10 microns. The specification does not disclose such a pore size range.

Claims 27-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is rejected because it is unclear if the glass plate to which the hydrogel is linked is the support to which the acrylate groups are bound.

Claim 27 recites the limitation "through said acrylate groups" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim. The acrylate groups in question appear to be bound to a glass plate. There is no antecedent basis for acrylates bound to a glass plate in the claim.

Claim 31 is rejected because the phrase "has limited nonspecific absorption" is vague and indefinite. The terms "limited" and "nonspecific" are relative terms which renders the claim indefinite. The terms "limited" and "nonspecific" are not defined by the claim, the specification

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does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term “nonspecific is vague because it is unclear what is or is not being absorbed.

Claims 33 and 37 are rejected because the metes and bounds of a nuclear assay are unclear. It is unclear what steps a nuclear assay would entail.

Claims 28-30, 32 and 35-36 are dependent claims that do not overcome the deficiencies of the independent claim that they are dependent therefrom.

Double Patenting

Applicant is advised that should claim 32 be found allowable, claim 36 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Terminal Disclaimer

The terminal disclaimer filed on 8/25/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 11/444,819 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Irene Marx/
Primary Examiner
Art Unit 1651